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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/715,998

11/18/2003

Scott R. Presnell

98-55D2

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10117

7590

10/03/2007

ZYMOGENETICS, INC.

INTELLECTUAL PROPERTY DEPARTMENT

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SEATTLE, WA 98102-3702

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,998

Applicant(s)

PRESNELL ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 24-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 24-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. This Office Action is in response to Applicant's response and amendments filed 7/16/2007. Applicant has cancelled claims 22 and 23. Applicant has amended claims 1, 3, 12, 24 and 39. Therefore, claims 1-21 and 24-45 are examined in this application.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

3. The Office notes that Applicant has amended the specification to remove embedded hyperlinks and capitalize trademarks.

Claim Rejections - 35 USC § 112, 1st paragraph maintained

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4a. The rejection of claims 1-21 and 24-45 under 35 U.S.C. 112, first paragraph, because the specification while enabling for polynucleotide sequence of SEQ ID NO: 1 or polynucleotide sequence of SEQ IDNO: 1 from nucleotide 1 to nucleotide 1682 or polynucleotide sequence of SEQ IDNO: 1 from nucleotide 1 to nucleotide 779 or polynucleotide sequence of SEQ IDNO: 1 from nucleotide 1 to nucleotide 833 or polynucleotide sequence of SEQ IDNO: 1 from nucleotide 1 to nucleotide 2887 or polynucleotide sequence of SEQ IDNO: 834 from nucleotide 1 to nucleotide 2887 polynucleotide sequence of SEQ IDNO: 1 from nucleotide 126 to nucleotide 779 or

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polynucleotide sequence of SEQ IDNO: 1 from nucleotide 126 to nucleotide 833 or
polynucleotide sequence of SEQ IDNO: 1 from nucleotide 834 to nucleotide 1682 or
polynucleotide sequence of SEQ IDNO: 1 from nucleotide 126 to nucleotide 1682 or
nucleotide sequence encoding SEQ ID NO: 2 from amino acid 20 to amino acid 237 or
nucleotide sequence encoding SEQ ID NO: 2 from amino acid 20 to amino acid 255 or
nucleotide sequence encoding SEQ ID NO: 2 from amino acid 256 to amino acid 538 or
nucleotide sequence encoding SEQ ID NO: 2 from amino acid 20 to amino acid 538 or
polynucleotide sequences complementary, does not reasonably provide enablement for
all possible nucleotide fragments contemplated by the Applicant is maintained for
reasons set forth in the Office Action dated 1/24/07 pages 5-10. Specifically, claims 1-
21 and 39 recite the phrase "a polynucleotide sequence" and "a polypeptide" and
thus, are broadly interpreted by the Examiner as reading upon: (i) fragments of SEQ ID
NOs: 1-2, including sequences only 10 amino acids or 60 nucleic acids in length (see
specification page 12 and page 23).

Applicant is essentially arguing that the Office is interpreting the claims
unreasonably broad. Applicant is arguing that the broadest possible interpretation of
language is not necessarily the broadest reasonable interpretation. Applicant contends
that the USPTO's new interpretation of the contested language of the claims renders
the claim so broad as it reads on any amino acid sequence that has six or more
residues. Applicant argues that this interpretation is unreasonable. In addition, such an
interpretation of the claims is entirely inconsistent with the specification, and hence
cannot be reasonable. In addition, Applicant assert that support for such an

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interpretation is not found in the application, for the simple reason that applicants never intended to make such a claim and therefore never described or enabled amino acid sequences that were 10 or more amino acid residues long. Further it is asserted that it is difficult to understand why an interpretation that was reasonable previously has been replaced by an interpretation that is contrary to the specification and claims of the patent. Applicant discusses the Office interpretation of the claims extensively on pages 13-16 of the response, specifically the inclusion of the fragments and variants. Applicant asserts that they describe the claimed fragments and variants both structurally and functionally. Applicant also discusses various fragments that are claimed and the biological function of the polypeptides (see pages 14-15 of the response). Applicant's arguments have been fully considered but are not found to be persuasive.

Contrary to Applicant's assertion that Office interpretation is broad and unreasonable, the Office is interpreting "a" as an indefinite article to read on (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO: 2. In contrast "the" is considered definite article and thus is interpreted to be limited to the sequence of interest only. In addition, the specification of the instant invention defines a polypeptide as a polymer of amino acid residues joined by peptide bonds, whether produced naturally or synthetically. Further, the specification teaches that polypeptides of less than about 10 amino acid residues are commonly referred to as "peptide". Although, the specification clearly identifies various fragments, the Office is interpreting the claims to read on for example, polypeptide fragment and variants that are 10 amino acids or longer because of the indefinite article "a". Although, the

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specification discloses the biological function of the α 11 ligand, there is no correlation between the various variants/fragments and the biological functions disclosed. In the absence of further guidance, these experiments (assay for proliferation, competition assays, binding assays etc.) would be more than routine experimentation for one of skilled in the art. It will require trial and error experimentation to identify the variants and fragments that are functional. Therefore, the rejection of record is maintained.

4b. The rejection of claims 1-21 and 24-45 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection* is maintained for reasons set forth in the Office Action dated 1/24/07 pages 10-12. The specification does not disclose all possible polynucleotide fragments of SEQ ID NO: 1 and fragments of polynucleotides encoding SEQ ID NO: 2 contemplated by the Applicant. Specifically, claims 1-21 and 39 lack written description support for the language reciting the phrases "a polynucleotide sequence" and "a polypeptide" and thus, are broadly interpreted by the Examiner as reading upon: (i) fragments of SEQ ID NOs: 1-2, including sequences only 10 amino acids or 60 nucleic acids in length (see specification page 12 and page 23).

Applicant has argued both the enablement and written description together (see 4a). Applicant's arguments have been fully considered but are not found to be

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persuasive. The Office has responded to the Applicant's arguments above in paragraph 4a. Therefore, the rejection of record is maintained.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5a. The rejection of claims 1-21 and 24-45 under 35 U.S.C. 102(e) as being anticipated by Donaldson et al. (U. S. Patent No. 6, 057, 128) is maintained for reasons set forth in the Office Action dated 1/24/07 pages 12-13. Applicant is asserting that the claims are drawn to polynucleotides encoding specific fragments of SEQ ID NO: 2 that are not taught by Donaldson et al. patent. Thus, it is argued that the instant claims are not anticipated by Donaldson et al. patent.

Applicant's arguments have been fully considered but are not found to be persuasive because the Office applied the Donaldson art based on the interpretation of the claims to read on various fragments of SEQ ID NO: 1 and 2 due to the of "a polynucleotide" or "a polypeptide". In addition, Applicant has not defined in the specification if "complementary" describes a full-length complementary sequence and thus the Examiner has interpreted it to include fragments that are at least 60 nucleic acids long. Therefore, claims of the instant invention is anticipated by Donaldson et al. (U. S. Patent No. 6, 057, 128).

Double Patenting,

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6a. The provisional rejection of claims 1-21 and 25-45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-36 of copending Application No. 11/537, 874 is maintained for reasons set forth in the Office Action dated 1/24/2007 page 15. Applicant has indicated that they will file a Terminal Disclaimer when the instant claims are allowable. However, since the instant claims are not allowable and no Terminal Disclaimer has been filed the provisional obviousness-type double patenting rejection is maintained.

6b. The provisional rejection of claims 1-21 and 25-45 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 11/537, 879 is maintained for reasons set forth in the Office Action dated 1/24/2007 page 15. Applicant has indicated that they will file a Terminal Disclaimer when the instant claims are allowable. However, since the instant claims are not allowable and no Terminal Disclaimer has been filed the provisional obviousness-type double patenting rejection is maintained.

Conclusion

7. No claims are allowable.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS

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September 30th, 2007.

**CHRISTINE J. SAOUD
PRIMARY EXAMINER**

Christine J. Saoud